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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/635,910

08/07/2003

John Butler

08203.0031

7825

22852

7590

09/15/2009

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EXAMINER

YANG, ANDREW

ART UNIT

PAPER NUMBER

3775

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/635,910	<b>Applicant(s)</b> BUTLER ET AL.	
	<b>Examiner</b> ANDREW YANG	<b>Art Unit</b> 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 69-90 and 93-100 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 69-90 and 93-100 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This action is in response to Applicant's amendment filed on June 4, 2009.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 69-74, 83-87, 93, 95, 98, and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Butler et al. (U.S. Patent No. 6254534) in view of Hart et al. (U.S. Patent No. 5848992).

Butler et al. discloses a surgical device 101 having a longitudinal axis, a distal ring 105, a proximal ring 110, and a wound retracting sleeve 106. The sleeve 106 extends between proximal ring 110 and the distal ring 105 (Figure 2), and movable between an insertion configuration and retracting configuration (Column 4, Lines 20-23). The sleeve retracts the wound laterally such that an overall amount of the sleeve 106 between the distal and proximal rings is less in the retracting position than in the insertion configuration (Column 5, Lines 3-6). Furthermore, the opening through the sleeve 106 has a diameter that approaches the diameter of the rings as the sleeve is moved to the retraction configuration (Figures 8A-8B). A sealing member 175 has ring member 171 with a recess 172 to releasably couple to ring 110. Furthermore it is considered that the sealing member is capable of being rotated in a sealed manner

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since the recess 172 and ring 110 are both smooth surfaces that would not inhibit rotation. Butler et al. fails to disclose the sealing member having three access ways.

Hart et al. teaches a surgical access device 10 having three access ways 18 (Figure 4). Having three access ways 18 allows the use of multiple surgical or other operable instruments within the operative region which increases the flexibility of procedures available within said region (Column 7, Lines 50-60). Each access way has a lip seal 42. Each access way terminates distally at a location coextensive with a distal surface of the sealing member facing the opening (Figure 3). The proximal surface of the seals can be dome shaped (Figure 6) and each seal can have a different diameter (Column 7, Lines 57-58). Although it is not disclosed that the seal is an iris valve it would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the seal as an iris valve, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a seal between an internal cavity and the external environment. In re Dailey and Eilers, 149 USPQ 47 (1966).

It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Butler et al. with a seal having three access ways with a lip seal or iris valve in view of Hart et al. allow for multiple instruments to be inserted into the operative region so as to increase the flexibility of surgical procedures available in the operative region.

Claims 69, 75-82, 88-90, 94, 96, 97, and 100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fadem et al. (U.S. Patent No. 6254533) in view of Hart et al. (U.S. Patent No. 5848992).

Fadem et al. discloses a surgical device 10 having a longitudinal axis a distal ring 14, a proximal ring 18, and a wound retracting sleeve. The sleeve extends between the rings from an insertion configuration to a retraction configuration so that the overall amount of sleeve extending between the rings is less in the retracting position (Column 4, Lines 50-52). The opening of the sleeve approaches a diameter of the rings as the distance between the rings is shortened since the sleeve is shortened until the sides are in a tight contiguous engagement with the sides of the wound (Column 4, Lines 50-52), meaning the sleeve is moved from a loose configuration where the opening is not as wide to the tight configuration where the sleeve retracts the wound opening and thus the opening of the sleeve becomes larger. A sealing member 108 is releasably coupled to the proximal ring 18 has an access way 114 that has a seal and is dome shaped. The access way 114 is located an axial distance proximal the proximal ring 118 and terminates distally at a location coextensive with a distal surface of the sealing member (Figure 4). The sealing member is configured to seal a surgeon's arm (Column 6, Lines 15-17) and is rotatable for the same reasons as why the seal of Butler et al is rotatable. Fadem et al. fails to disclose the sealing member having three access ways with their central axes converging at toward one another as the extend through the proximal ring.

Hart et al. teaches a surgical access device 10 having three access ways 18 (Figure 4). Having three access ways 18 allows the use of multiple surgical or other

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operable instruments within the operative region which increases the flexibility of procedures available within said region (Column 7, Lines 50-60). Each access way has a lip seal 42. Each access way terminates distally at a location coextensive with a distal surface of the sealing member facing the opening (Figure 3). The proximal surface of the seals can be dome shaped (Figure 6) and each seal can have a different diameter (Column 7, Lines 57-58). Although it is not disclosed that the seal is an iris valve it would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the seal as an iris valve, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a seal between an internal cavity and the external environment. In re Dailey and Eilers, 149 USPQ 47 (1966).

It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Fadem et al. with a seal having three access ways with a lip seal or iris valve in view of Hart et al. allow for multiple instruments to be inserted into the operative region so as to increase the flexibility of surgical procedures available in the operative region.

It is noted that provide three seals on the domed surface 108 of Fadem et al would cause the central axes of each access way to converge as they extend distally through the proximal ring.

***Response to Arguments***

Applicant's arguments with respect to claims 69-90 and 93-95 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **ANDREW YANG** whose telephone number is (571)272-3472. The examiner can normally be reached on IFP.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on (571)272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew Yang/  
Examiner, Art Unit 3775

/Thomas C. Barrett/  
Supervisory Patent Examiner, Art  
Unit 3775